.....

(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. 7071

To provide for the acceleration of access to clinical therapies for the treatment of amyotrophic lateral sclerosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. FORTENBERRY introduced the following bill; which was referred to the Committee on _____

A BILL

To provide for the acceleration of access to clinical therapies for the treatment of amyotrophic lateral sclerosis, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Accelerating Access to Critical Therapies for ALS Act".

SEC. 2. GRANTS FOR RAPID DEVELOPMENT OF THERAPIES FOR ALS AND OTHER RAPIDLY PROGRESSING NEURODEGENERATIVE DISEASES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall award grants to eligible entities for the provision of investigational drugs through an expanded access program pursuant to section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for individuals for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis or another rapidly progressing neurodegenerative disease.

(b) VESTED AUTHORITY.—For purposes of development of an investigational drug pursuant to subsection (a), the Secretary may vest authority in the participating clinical trial site or sites to make the determination under subsection (b)(2), (c)(6), or (c)(7), as applicable, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(c) TIMING.—Not later than 60 days after the date of submission of an application for a grant under this section—

(1) the Secretary, acting through the Director of the National Institutes of Health, shall determine whether to award the grant; and

(2) the Secretary acting through the Commissioner of Food and Drugs (or by vesting authority

in the participating clinical trial site, as applicable) shall make the determinations required of the Secretary under subsection (b) or (c), as applicable, of section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for the provision of the investigational drug to occur.

(d) DEFINITIONS.—In this section:

(1) The term "Director" means the Director of the National Institutes of Health.

(2) The term "eligible entity" means an entity that is—

(A) a small business concern (as defined in section 3(a) of the Small Business Act (15 U.S.C. 632(a)) that is the sponsor of a drug that is the subject of an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)); or

(B) a participating clinical trial site for such an applicant.

(3) The term "participating clinical trial" means a phase 2 or phase 3 clinical trial conducted pursuant to an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a) of the Public

Health Service Act (42 U.S.C. 262(a)) to investigate a drug intended to treat amyotrophic lateral sclerosis or another rapidly progressing neurodegenerative disease.

(4) The term "participating clinical trial site" means a health care facility at which patients participating in a participating clinical trial receive treatment through such trial.

(5) The term "Secretary" means the Secretary of Health and Human Services.

(c) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(A) $75,000,000 for each of fiscal years 2021 and 2022; and

(B) $150,000,000 for each of fiscal years 2023 and 2024.

(2) GIFTS, GRANTS, AND OTHER DONATIONS TO FOUNDATION.—

(A) ACCEPTANCE.—Pursuant to section 499(c) of the Public Health Service Act (42 U.S.C. 290b(c)), the Foundation for the National Institutes of Health may solicit and accept gifts, grants, and other donations, estab-

lish accounts, and invest and expend funds in support of carrying out this section.

(B) USE.—In addition to the amounts made available pursuant to the authorizations of appropriations in paragraph (1), the Director may use, without further appropriation, any funds derived from a gift, grant, or other donation accepted pursuant to subparagraph (A).

(f) REVIEW AND EXPANSION.—Not later than 18 months after the date of the enactment of this Act—

(1) the Secretary of Health and Human Services shall convene an independent review panel that includes representatives of patients, researchers, drug sponsors, and government agencies; and

(2) the independent review panel shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the findings and conclusions of the panel with respect to the design and implementation of the program under this section for 2023 and 2024.

SEC. 3. FDA CENTER OF EXCELLENCE FOR NEURODEGENERATIVE DISEASES.

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1015. CENTER OF EXCELLENCE FOR NEURODEGENERATIVE DISEASES.

"(a) ESTABLISHMENT.—Not later than September 2021, the Secretary shall establish within the Food and Drug Administration a center of excellence, to be known as the Center of Excellence for Neurodegenerative Diseases (in this section referred to as the 'Center of Excellence').

"(b) DUTIES AND AUTHORITIES.—The Center of Excellence shall have duties and authorities similar to those of the Center of Excellence for Oncology established under section 1014, including the duties and authorities of the Center of Excellence for Oncology with respect to Project Facilitate.".